

## **REMARKS**

Claims 6-9, 26, 27 and 32-34 are pending in this application. Claims 6-9, 26, 27 and 32-34 are amended herein to clarify and more particularly define the invention. New claims 35 and 36 are added herein. Support for these amendments and new claims is found in the language of the original claims and throughout the specification, as set forth below. Thus, no new matter is added by these amendments and new claims and their entry and consideration are respectfully requested. In light of the amendments, new claims and following remarks, applicants respectfully request reconsideration of this application and allowance of the claims to issue.

### **I. Recordation of Interview Summary**

Applicants wish to thank Examiner Qian Janice Li and Supervisory Patent Examiner Joseph Woitach for granting the request for and participating in the telephonic interview held on January 29, 2008 with applicants' representatives, Dr. Mary Miller and Dr. Alice M. Bonnen. The substance of the interview is discussed below.

### **II. Rejection under 35 U.S.C. § 112**

A. The Action states that claims 6 and 9 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement.

As presented herein, claim 6 recites an isolated nucleic acid sequence encoding an Epstein Barr Virus (EBV) peptide immunochemically reactive with an antibody to the EBV VCA-p18 or VCA-p40 proteins, comprising an epitope of the VCA-p18 or VCA-p40 protein, encoded within the EBV open reading frames BFRF3 and BdRF1, respectively, and wherein said antibody to VCA-p18 is produced by the hybridoma deposited at the European Collection of Animal Cell Cultures under deposit number 93020413 or 93020412 and said antibody to VCA-p40 is produced by the hybridoma deposited at the European Collection of Animal Cell Cultures under deposit number 93020414, and wherein the reaction of the EBV peptide and the antibody to VCA-p18 in an ELISA results in an optical density reading greater than 0.5 at 450nm and the combination of the peptide and the antibody to VCA-p40 in an ELISA results in an optical density greater than 1.0 at 450nm.

Support for these amendments is found throughout the specification, for example, at least in Example 4 and Figures 5 and 6.

Thus, in claim 6 as presented herein, the nucleic acid sequences encode peptides comprising an epitope of the VCA-p18 or VCA-p40 protein. The peptides encoded by the nucleic acid sequences of claim 6 are further defined by their immunoreactivity with hybridoma-derived antibodies to VCA-p18 and VCA-p40 having European Collection of Animal Cell Cultures deposit numbers 93020413 or 93020412 (VCA-p18) or deposit number 93020414 (VCA-p40), respectively, and by their ability, when reacted in an ELISA with the antibodies of claim 6, to result in an optical density reading of greater than 0.5 (VCA-p18) or greater than 1.0 (VCA-p40) at 450nm.

Furthermore, the specification demonstrates actual reduction to practice of the nucleic acids of claim 6 and in particular, provides several examples of peptides comprising epitopes of this invention. Specifically, the present specification teaches that peptides encoded by the nucleic acid sequences of the present invention were synthesized, each having a length of 12 amino acids and an overlap of 11 amino acids of the amino acid sequence of the open reading frame of BFRF3 and BdRF1 (*See*, specification, page 30, last paragraph, through page 32). Figures 5A and 5B show PEPSCAN results of an analysis of the peptides of the present invention using the two VCA-p18 monoclonal antibodies of claim 6. Figure 6 shows the PEPSCAN results of an analysis of the peptides using the VCA-p40 monoclonal antibodies of claim 6.

Figure 5A shows that 12-mer peptides beginning with amino acid 113 through amino acid 120, respectively, are peptides with greatest reactivity (i.e., OD<sub>450</sub> greater than 0.5) with the VCA-p18 antibodies of claim 6.

Figure 5B shows that 12-mer peptides beginning with amino acid 126 through amino acid 128, respectively, are peptides with greatest reactivity (i.e., OD<sub>450</sub> greater than 0.5) with the VCA-p18 antibodies of claim 6.

Furthermore, Figure 6 shows that 12-mer peptides beginning with amino acid 285 through amino acid 293, respectively, are peptides with the greatest reactivity (OD<sub>450</sub> greater than 1.0) with the VCA-p40 antibodies of claim 6.

Thus, the specification provides a total of 20 examples of peptides encoded by the nucleic acids of claim 6. Accordingly, as evidenced by the disclosure of the present specification, one of skill in the art would recognize that applicants were in possession of these peptides and thus the nucleic acid sequences of claim 6 at the time the present application was filed.

Applicants note that the Office Action states that the proteins reactive with the antibodies may be structurally distinct and cites to Table 1 of the specification for support. Specifically, the Office Action asserts that Table 1 shows that the serum proteins reactive with applicants' antibody have different domain combinations and thus are structurally different.

Applicants respectfully point out that Table 1 of the specification shows the immunological reactivity of sera from 15 EBV positive patients (NOT the antibodies of the invention) to peptides of the invention. Thus, Table 1 does not show reactivity with the antibodies of the invention and therefore cannot be used to support the proposition that the specification fails to provide an adequate description for the genus of the nucleic acid sequences encompassed by the claims as asserted in the Office Action. As clearly described above, the peptides reactive with each of the monoclonal antibodies of claim 6 do have structural similarities and are easily identified by one of skill in the art based on a reading of the present specification.

Therefore, applicants respectfully submit that all of the members of the genus of nucleic acids of claim 6 are adequately defined both structurally and functionally, leading one of ordinary skill in the art to the reasonable conclusion that applicants were in possession of the invention of claim 6 at the time this application was filed.

Claim 9 depends from claim 6 and recites a vector comprising the nucleic acid sequence of claim 6. Because the nucleic acid sequence of claim 6 is adequately described in the specification, the vector of claim 6 is adequately described as well.

Thus, at least for the reasons set forth above, applicants believe that this rejection has been overcome and its withdrawal and allowance of the pending claims are respectfully requested.

**B.** The Action states that claims 6 and 9 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement.

As discussed above, the subject matter of claims 6 and 9 is adequately described in the present specification. The specification not only adequately discloses the genus of nucleic acid sequences of claim 6, but also provides detailed teachings of how to make and use these nucleic acid sequences, (*See*, in particular, Figures 5 and 6 and the Examples set forth on pages 22-36), wherein numerous working examples are provided of the production and testing of numerous peptides and nucleic acids of this invention. Thus, applicants respectfully submit that the present invention is adequately enabled and applicants thereby respectfully request withdrawal of this rejection.

### **III. Rejection under 35 U.S.C. § 102(b)**

**A.** The Action states that claims 6-9, 26, 27 and 32-34 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Laux et al. (*EMBO J.* 7:769-774 (1988)). Specifically, the Action states that Laux et al. teaches a nucleic acid sequence comprising a subsequence of instant SEQ ID NO:1 which encodes at least 12 contiguous amino acids of EBV VCA-p18 (the amino acid sequence of SEQ ID NO:5). The Office Action further states that Laux et al. teaches a nucleic acid sequence comprising instant SEQ ID NO:3, which encodes 12 contiguous amino acids of an EBV VCA-40 protein. On this basis, the Office Action concludes that Laux et al. anticipates the instant claims. Applicants respectfully disagree and traverse this rejection.

As discussed during the January 29, 2008 telephone interview and as set forth in the previous response dated July 23, 2007 (hereinafter "the July 23, 2007 response"), Laux et al. fails to disclose the nucleotide sequences of SEQ ID NO:1 or SEQ ID NO:3 or any subsequences thereof encoding 12 contiguous amino acids (including SEQ ID NO:5), as claimed herein. In response to the arguments and alignments presented by applicants in the July 23, 2007 response, the Examiner provided printed copies of EMBL Nucleotide Sequence database search results, which are alleged to contain the details of the alignment with the Laux et al. sequence. The accession numbers provided with these search results are AJ507799.1 and V01555.1 and show reference sequences having dates after the priority date of this application. As explained during the interview and in the July 23, 2007 response, the nucleotides shown in these reference sequences as aligning with those of the present invention are not any of the sequences disclosed in Laux et al. In addition, it is important to note that these reference sequences have never been cited in any Office Action to reject the claimed sequences of the present invention and further these reference sequences are not proper prior art references since the dates shown for these accession numbers, April 15, 2005 (AJ507799.1) and April 18, 2005 (V01555.1), respectively, do not precede the filing date of the present application.

During the January 29, 2008 telephone interview applicants' representatives requested that a reference be provided that properly supports this rejection, if such reference exists, for the portions of the database for which the Patent Office alignments were run. However, applicants have not received any such a reference despite follow-up telephone calls to Examiner Li on February 11, 2008 and March 5, 2008. Thus, in the absence of any prior art document to support this rejection, applicants respectfully request its withdrawal.

**B.** The Action states that claims 6-9, 26, 27 and 32-34 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Bankier et al. (*Mol. Biol. Med.* 1:425-445 (1983)). Specifically, the Action states that Bankier et al. teaches a nucleic acid sequence comprising instant SEQ ID NO:1, which encodes at least 12 contiguous amino acids of EBV VCA-p18 (the amino acid sequence of SEQ ID NO:5). The Action further states that Bankier et al. teaches a nucleic acid sequence comprising a sequence that shares 98.8% homology with instant SEQ ID NO:3

(subsequence thereof), which encodes 12 contiguous amino acids of an EBV VCA-40 protein. On this basis, the Action concludes that Bankier et al. anticipates the instant claims. Applicants respectfully disagree and traverse this rejection.

As discussed during the January 29, 2008 telephone interview and as set forth in the previous response dated July 23, 2007 (hereinafter "the July 23, 2007 response"), Bankier et al. fails to disclose the nucleotide sequences of SEQ ID NO:1 or SEQ ID NO:3 or any subsequences thereof encoding 12 contiguous amino acids (including SEQ ID NO:5), as claimed herein. In response to the arguments and alignments presented by applicants in the July 23, 2007 response, the Examiner provided printed copies of EMBL Nucleotide Sequence database search results, which are alleged to contain the details of the alignment with the Bankier et al. sequence. The accession numbers provided with these search results are AJ507799.1 and V01555.1 and show reference sequences having dates after the priority date of this application. As explained during the interview and in the July 23, 2007 response, the nucleotides shown in these reference sequences as aligning with those of the present invention are not any of the sequences disclosed in Bankier et al. In addition, it is important to note that these reference sequences have never been cited in any Office Action to reject the claimed sequences of the present invention and further these reference sequences are not proper prior art references since the dates shown for these accession numbers, April 15, 2005 (AJ507799.1) and April 18, 2005 (V01555.1), respectively, do not precede the filing date of the present application.

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#### IV. New Claims

New claims 35 and 36 are added herein. Support for these claims can be found in the language of the original claims and throughout the specification, for example, at least in claims 7 and 8 and on page 13, second full paragraph of the specification. Thus, no new matter is believed to be added by entry of these new claims. Further, these claims are believed to be free of the pending rejections for the same reasons set forth above explaining why claims 6-9, 26, 27 and 32-34 are free of the pending rejections and their entry and allowance are respectfully requested.

Having addressed all of the issues raised by the Examiner in the pending Office Action, applicants believe the claims as presented herein to be in condition for allowance, which action is respectfully requested. The Examiner is encouraged and invited to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue.

The Commissioner is authorized to charge Deposit Account No. 50-0220 in the amount of \$1,270.00 (\$810.00 for a Request for Continued Examination and \$460.00 as fee for a two-month extension of time). This amount is believed to be correct. However, the Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,



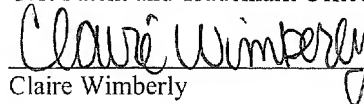
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#### CERTIFICATION OF ELECTRONIC TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on March 17, 2008.

  
Claire Wimberly